IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

SUSAN ANTONUCCI, CARL C. ANTONUCCI,	)	
Plaintiffs,	)	1:20-CV-00115-CCW
v.	)	
BOSTON SCIENTIFIC CORPORATION,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Susan Antonucci has had multiple pelvic mesh devices implanted over the years to attempt to treat health conditions related to aging and perimenopause. Two of those devices were made by Defendant Boston Scientific Corporation—the Pinnacle Pelvic Floor Repair Kit and the Lynx Suprapubic Mid-Urethral Sling System. But, when Plaintiffs filed their short-form Complaint in the MDL court in 2013, *see* ECF No. 1, they identified only the Pinnacle as being the alleged source of Ms. Antonucci's injuries. Now, with discovery long closed and with the case nearly trial-ready, Plaintiffs seek leave to amend their Complaint to include claims related to the Lynx. *See* ECF No. 111. In a related motion, Defendant Boston Scientific asks that the Court exclude certain kinds of case-specific evidence related to the Lynx from being presented at trial. *See* ECF No. 109. For the reasons that follow, Plaintiffs' Motion for Leave to Amend will be DENIED, and Boston Scientific's Motion *in Limine* will be GRANTED IN PART.

I. Background

Ms. Antonucci had the Lynx implanted in 2006 "to try to correct bladder prolapse and urinary incontinence she had been experiencing due to aging and perimenopause." ECF No. 111 at 2. Because the Lynx did not "do its intended job concerning the prolapse," Ms. Antonucci had

the Pinnacle implanted in 2008. *Id.* Ms. Antonucci has since undergone multiple surgeries related to these Boston Scientific devices (and other manufacturers' pelvic mesh devices), *see* ECF No. 117 at 2), culminating in the removal of most of both the Lynx and the Pinnacle in 2012 and 2014. *See* ECF No. 111 at 2.

Plaintiffs filed their nine-count short-form Complaint in the MDL court in June 2013. *See* ECF No. 1. In it, they assert claims against Boston Scientific related only to the Pinnacle. *See id.* at ¶¶ 6, 8–9, and 13.[1] Likewise, Plaintiffs did not identify the Lynx on their "Plaintiff Profile Form," which was submitted in July 2013. *See* ECF No. 117 at 2. Plaintiffs' case was then "activated for discovery" by the MDL court in early 2018, *see* ECF No. 111. at 4, at which time the MDL court also set relevant discovery deadlines. Pursuant to those orders, Plaintiffs' "Fact Sheet" was due by March 19, 2018; written discovery requests were due to be served by May 18, 2018; and all depositions and discovery were to be completed by October 4, 2018. *See* ECF No. 25; *see also* ECF No. 117 at 2. And, although the fact that Ms. Antonucci had been implanted with a Lynx is mentioned or discussed in some discovery materials—for example, Dr. Rosenzweig's expert report, ECF No. 111-2, and Ms. Antonucci's deposition, ECF No. 111-1—the Lynx is not listed on Plaintiffs' "Fact Sheet," *see* ECF No. 111-4 at 6, nor does it appear to be included or mentioned in either Plaintiffs' written discovery requests or Plaintiffs' responses to Defendant's written discovery requests. *See* ECF No. 117 at 40–73.

On May 12, 2020, this case was transferred from the MDL Court to the Western District of Pennsylvania for trial, and it was then reassigned to the undersigned on October 23, 2020. *See*

[1] Asserting claims for: negligence (Count I); strict liability – design defect (Count II); strict liability – manufacturing defect (Count III); strict liability – failure to warn (Count IV); breach of express warranty (Count V); breach of implied warranty (Count VI); loss of consortium on behalf of Plaintiff-Husband Carl Antonucci (Count VII); discovery rule, tolling, and fraudulent concealment (Count VIII); and punitive damages (Count IX). *See* ECF No. 1 at ¶ 13.

ECF No. 34. On February 19, 2021, the Court entered its Final Pretrial Order, setting deadlines for filing pretrial materials. *See* ECF No. 88. Pursuant to that Order, Plaintiffs filed their Pretrial Statement on March 29, 2021, and for the first time proposed amending their Complaint to include Lynx-related claims. *See* ECF No. 102; *see also* ECF No. 117 at 3. Because Boston Scientific opposed the proposed amendment, the parties alerted the Court to the dispute and proposed the instant motions as an efficient method for resolving the Lynx-related issues. *See* ECF No. 105. On April 26, 2021, the Court entered an Order setting a briefing schedule and staying all pretrial deadlines until the instant motions are resolved. *See* ECF No. 106. Now that both motions are fully briefed, the Lynx-related issues are ripe for decision.

II. Plaintiffs' Motion for Leave to Amend Will Be Denied

Whether to grant a motion for leave to amend "generally falls within the District Court's discretion." *Mullin v. Balicki*, 875 F.3d 140, 149 (3d Cir. 2017). And, while "[g]enerally, Rule 15 motions should be granted," *United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016), "[a] district court may deny leave to amend a complaint if a plaintiff's delay in seeking amendment is undue, motivated by bad faith, or prejudicial to the opposing party." *Cureton v. NCAA*, 252 F.3d 267, 272-73 (3d Cir. 2001). Furthermore, "[i]n determining whether leave to amend might reasonably be denied, courts are guided by the *Foman* factors, named for the Supreme Court's decision in *Foman v. Davis*." *Mullin*, 875 F.3d at 149 (citing 371 U.S. 178 (1962). The *Foman* factors are "not exhaustive," but include such relevant considerations as "undue delay, bad faith or dilatory motive on the part of the movant; repeated failure to cure deficiencies by amendments previously allowed; prejudice to the opposing party; and futility." *Id.* Finally, "[a]ll factors are not created equal, however, as

'prejudice to the non-moving party is the touchstone for the denial of an amendment.'" *Id.* at 150 (quoting *Arthur v. Maersk, Inc*., 434 F.3d 196, 204 (3d Cir. 2006)).

Importantly, "[t]he mere passage of time does not require that a motion to amend a complaint be denied on grounds of delay." *Cureton*, 252 F.3d at 273 (citing *Adams v. Gould, Inc.*, 739 F.2d 858, 868 (3d Cir. 1984)). However, undue delay—that is, delay that is "protracted and unjustified," *Mullin*, 875 F.3d at 151,may warrant denial of leave to amend "when it places an unwarranted burden on the court or when the plaintiff has had previous opportunities to amend." *Estate of Oliva v. New Jersey*, 604 F.3d 788, 803 (3d Cir. 2010) (citing *Bjorgung v. Whitetail Resort, LP*, 550 F.3d 263, 266 (3d Cir. 2008)). Indeed, the United States Court of Appeals for the Third Circuit has "refused to overturn denials of motions for leave to amend where the moving party offered no cogent reason for the delay in seeking the amendment." *CMR D.N. Corp. & Marina Towers Ltd. v. City of Phila*., 703 F.3d 612, 629 (3d Cir. 2013) (collecting cases). "Thus, while bearing in mind the liberal pleading philosophy of the federal rules…the question of undue delay requires that we focus on the movant's reasons for not amending sooner." *Cureton*, 252 F.3d at 273 (citing *Adams*, 739 F.2d. at 864, 868).

Here, Plaintiffs' delay in seeking amendment has been excessive. Despite being in possession of the facts needed to assert Lynx-based claims since before they originally filed suit in 2013—as Plaintiffs' briefing notes, Ms. Antonucci had the Lynx implanted in 2006, and by 2013 had had at least two surgeries (implantation of the Pinnacle in 2008 and a partial revision of the Lynx and Pinnacle in 2012) to attempt to remediate problems related to the Lynx—Plaintiffs failed to take any action to include Lynx-related claims until they filed their pretrial statement in late March 2021. Even if we measure from when this case was "activated" for discovery in 2018, Plaintiffs waited more than three years to seek amendment. And, importantly, Plaintiffs fail to

explain in any meaningful way why they failed to seek amendment sooner. Indeed, the best explanation offered by Plaintiffs for the delay is that "[t]he omission of the Lynx product in the initial short form complaint was not discovered until the parties were drafting their joint pre-trial order." ECF No. 121 at 2. That is, Plaintiffs did not include—or move to include—Lynx-related claims because of what Plaintiffs term "a minute administerial oversight." ECF No. 111 at 6.

Indeed, Plaintiffs frame their motion as merely asking the Court to allow them to "complete the ministerial task of marking the box next to the Lynx" on their short-form Complaint. ECF No. 111 at 5. They further propose that such a change will cause no prejudice to Boston Scientific because it "was made fully aware through testimony, medical records, and expert reports that Mrs. Antonucci had two of their products implanted." *Id.* at 7. But, whether or not Plaintiffs considered this suit to be a "dual products case," ECF No. 111 at 8, Boston Scientific correctly points out that "Boston Scientific's knowledge that a plaintiff has received a particular product does not put it on notice that the plaintiff is pursuing legal action in relation to that product." ECF No. 117 at 10; *see also CMR,* 703 F.3d at 630 (denying leave to amend and noting "it is a plaintiff's burden to set forth the grounds on which it rests a claim for relief.") (citing Fed. R. Civ. P. 8(a)).

Boston Scientific maintains that allowing Plaintiffs to amend their Complaint now would cause prejudice to Boston Scientific because, with respect to any Lynx-related claims, "Boston Scientific did not pursue its own discovery, develop its defenses, or retain any experts to opine on such claims" in this case. ECF No. 117. at 7. The Court agrees with this assessment. *See Graham v. Progressive Direct Ins. Co*., 271 F.R.D. 112, 122 (W.D. Pa. 2010) (quoting *Cureton v. NCAA*, 252 F.3d at 273 ("As to prejudice, the Court of Appeals has 'considered whether allowing an amendment would result in additional discovery, cost, and preparation to defend against new facts or new theories.'")). Boston Scientific may have known that Ms. Antonucci had been implanted

with a Lynx device, but, absent notice that Plaintiffs would be pursuing claims related to the Lynx, Boston Scientific had no reason to spend time or resources on developing defenses to such claims.

In sum, Plaintiffs have waited too long to seek amendment to add Lynx-related claims. This delay, for which Plaintiffs offer no cogent explanation, would prejudice Boston Scientific if amendment were allowed. As such, Plaintiffs' Motion for Leave to Amend will be denied.

III. Defendant's Motion *in Limine* Will Be Granted in Part

In its Motion *in Limine*, Boston Scientific asks the Court to exclude eight defined categories of Lynx-related evidence from the trial of this case:

> 1) testimony from the implanter [of the Lynx] Dr. David Hulbert, who has not been deposed;
>
> 2) testimony regarding any Lynx adverse event warnings that Dr. Hulbert may have reviewed or received, including expert opinion testimony regarding the adequacy of such warnings;
>
> 3) testimony regarding the Lynx from Dr. Michael Bonidie, the surgeon who revised Plaintiff's Lynx sling, other than the facts that he observed the Lynx, may have concluded that revising it was necessary, and did revise it;
>
> 4) testimony regarding the design, development and manufacture of the Lynx, including expert opinion testimony regarding design and manufacturing defects;
>
> 5) Lynx sales and marketing materials;
>
> 6) Lynx-related regulatory materials;
>
> 7) Lynx warnings and labels; and
>
> 8) third-party, non-medical record documents related to the Lynx, such as clinical studies and medical society position statements.

ECF No. 109 at 2–3. According to Boston Scientific, because Plaintiffs failed to plead Lynx-related claims, such evidence should be excluded because it would be irrelevant, misleading, and/or unfairly prejudicial. *See* ECF No. 110 at 3–5. In opposition, Plaintiffs argue that Boston Scientific's Motion *in Limine* should be denied because (1) "a blanket exclusion of Lynx-related evidence would prejudice Plaintiffs from offering significant aspects of Ms. Antonucci's medical

history;" and (2) "the risks associated with all polypropylene mesh products are the same…[thus] evidence concerning the dangers associated with polypropylene in general is plainly relevant to whether the company was on notice of its dangerous propensities." ECF No. 116 at 2–3.

In response, Boston Scientific expressly states that its Motion *in Limine* is limited to "case-specific evidence of alleged defect, causation, liability and damages necessary to support the proposed Lynx claims, such as the testimony of Drs. Hulbert and Bonidie and the Lynx-related opinion testimony of Plaintiffs' case-specific expert." ECF No. 120 at 2. Furthermore, Boston Scientific states that it "is not seeking to exclude medical records and similar evidence that reflect the mere fact that [Ms. Antonucci] received a Lynx sling and other similar, basic information from her medical history," nor does its Motion *in Limine* "raise the question of generic, common-issue evidence of 'other products' that Plaintiffs may argue are relevant to their existent Pinnacle-related claims." *Id.*

Based on the foregoing, the Court agrees, in general, with Boston Scientific's argument that case-specific Lynx evidence is not relevant to Plaintiffs' Pinnacle claims and, even if it were, its probative value would be substantially outweighed by the danger of unfair prejudice to Boston Scientific. Specifically, the evidence described in categories 1 and 2 appears to be relevant only to Ms. Antonucci's individual experience with the Lynx; as such, that evidence does not appear to have any tendency to make any fact of consequence with respect Plaintiffs' claims regarding the Pinnacle more probable than without it. *See* Fed. R. Evid. 401. Similarly, evidence falling within the scope of categories 4 through 8 appears to relate to Boston Scientific's development and marketing of the Lynx in particular, as opposed to polypropylene mesh medical devices in general, and likewise would not appear to have any relevance to Plaintiffs' Pinnacle claims. Accordingly, Boston Scientific's Motion *in Limine* will be granted with respect to categories 1, 2,

and 4 through 8, without prejudice to the Court's ability to revisit this ruling at trial in light of the particular content of a piece of evidence and the context within which that evidence is offered.

With respect to category 3, it is the Court's understanding that Ms. Antonucci's course of treatment with the Pinnacle is closely related to her treatment with the Lynx. As such, the Court cannot definitively say at this juncture that limiting Dr. Bonidie's testimony as Boston Scientific suggests would not also preclude evidence relevant to Plaintiffs' Pinnacle claims. Therefore, Boston Scientific's Motion *in Limine* will be denied with respect to category 3, without prejudice to the Court's ability to revisit this ruling at trial in light of the particular content of a piece of evidence and the context within which that evidence is offered.

IV. Conclusion

For the foregoing reasons, Plaintiff's Motion for Leave to Amend, ECF No. 111, is hereby DENIED and Defendant's Motion *in Limine,* ECF No. 109, is hereby GRANTED IN PART as set forth above.

IT IS SO ORDERED.

DATED this 28th day of June, 2021.

BY THE COURT:

/s/ Christy Criswell Wiegand
CHRISTY CRISWELL WIEGAND
United States District Judge

cc (via ECF email notification):

All Counsel of Record